

**Amendment and Response**

Stefan SANNER

Serial No.: 09/446,323

Filed: 20 March 2000

For: DEVICE FOR TAKING AND EXAMINING SAMPLES

**Remarks**

The Office Action dated 11 December 2001 has been received and reviewed. With claims 1-3, 7-8, and 10-12, having been amended, claims 4-6 and 9 having been canceled, and claims 13-21 having been added, the pending claims are claims 1-3, 7-8, and 10-21. Reconsideration and withdrawal of the rejections are respectfully requested.

**In the Drawings**

The Office Action objected to the drawings for failing to include various reference numerals. Figures 2, 3, and 4 have been amended as shown in the attached redline markups. Corrected drawings are also included herewith. Reconsideration and withdrawal of the drawing objections are respectfully requested.

**In the Specification**

The Office Action also addressed the form of the Abstract. While the Office Action suggests that certain language should be avoided, the Abstract appears to meet PTO requirements and no amendments are made herein.

*means  
maintain***In the Claims****The 35 U.S.C. §112, Second Paragraph, Rejection**

Claims 1-12 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More particularly, the Office Action notes several formal issues in the claims.

Claims 1-3, 7-8, and 10-12 have been amended as shown in Appendix A. These amendments were made strictly to clarify the invention and not to limit the scope of the invention in any way. It is believed that these amendments are sufficient to remove the 35

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U.S.C. §112, second paragraph, rejections. Accordingly, reconsideration of the claims and withdrawal of the rejections are respectfully requested.

**The 35 U.S.C. §102(b) Rejections****Rejection of claims 1-3, 8, and 11-12 in view of U.S. Pat. No. 5,393,496 (Seymour I)**

Claims 1-3, 8, and 11-12 were rejected under 35 U.S.C. §102(b) as being anticipated by Seymour I (U.S. Patent No. 5,393,496). Applicant respectfully traverses this rejection for at least the following reasons.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art document." MPEP §2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Id.* at §2131.

Claim 1, from which claims 2-3, 8, and 11 depend, recites a device for taking and examining samples. The claim recites a housing in which a cartridge, a testing means, and a sample-taking means are positioned. The cartridge is displaceable within the housing such that a sample introduced by the sample-taking means is operable to form a sample mixture with a content of the cartridge. Further, the testing means is displaceable within the housing such that the testing means can be brought in contact with the sample mixture for analyzing the sample mixture. Similarly, claim 12 recites a kit for taking and examining samples wherein the kit includes a sample-taking means for taking a sample; a housing with a cartridge arranged therein; and a testing means. The sample-taking means and the testing means are introducible into the housing and the testing means is operable to be displaced after having been introduced into the housing.

The identified portions of Seymour I illustrate a saliva sampling device 1110 having a sample container 1111 with a cap 1112, a saliva collector 1113, a collection container 1114 and a sample adequacy system 1115. The sample container 1111 also includes a retaining ridge 1133 and a filtering system 1134. Once an adequate amount of saliva has been collected, the saliva

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collector 1113 is inserted into the sample container 1111 (after the cap 1112 has been removed therefrom), in order to mix the buffering solution 1128 and the sample of saliva together. When the sample container 1111 is inserted into the collection container 1114 and pressed downward, the seal-breaking member 1121 breaks the breakable seal 1118 and the mixture of the buffering solution 1128 and the sample of saliva flows into the collection container 1114 through the filtering system 1134. The collection container 1114 with the mixture of the buffering solution 1128 and the saliva contained therein is then sealed by the cap 1112. *See* Figures 47-49 and 53-57 and specification column 16, line 47 - column 17, line 60. However, there is no testing means as claimed associated with the container 1111, the collector 1113, or the container 1114 in Seymour I.

Nonetheless, the Office Action alleges that testing disks 1634 and 1734 are provided. Applicant first notes that testing disk 1634 is described as part of automatic testing mechanism 1626 (*see* column 21, lines 18-28). The automatic testing machine is a separate device to which a sample container (e.g., 1215 of Figures 58-62) may be attached after sample collection. That is, testing disk 1634 is not, contrary to the Office Action's assertion, "contained within a housing 1114, 1214 [, and] 1714" (*see* Office Action, page 5). Moreover, Applicant notes that reference numeral 1734 refers to "a bore" in Figure 91 (*see* Office Action, column 22, lines 7-11), not to a testing device of any kind.

Applicant submits that an anticipation rejection of claims 1 and 12 is unsupported as each and every element of these claims is not identified in Seymour I. For example, with respect to claim 1, there is no teaching identified of a housing having positioned therein a cartridge, a testing means, and a sample-taking means. Moreover, there is no teaching identified of a housing having positioned therein a cartridge, a testing means, and a sample-taking means wherein the testing means is displaceable within the housing such that the testing means can be brought into contact with the sample mixture for analysis.

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With respect to claim 12, there is no teaching of, for example, a sample-taking means and a testing means introducible into a housing wherein the testing means is operable to be displaced after introduction.

Claims 2-3, 8, and 11 are also submitted to be allowable both in view of their dependence on claim 1 and further in view of the unique subject matter addressed therein.

For at least these reasons, Applicant requests reconsideration and withdrawal of the rejection of claims 1-3, 8, and 11-12 in view of Seymour I.

Rejection of claims 1-3, 8, and 11-12 in view of EP 520,408 A2 (Seymour II)

Claims 1-3, 8, and 11-12 were rejected under 35 U.S.C. §102(b) as being anticipated by Seymour II (EP 520,408 A2). Applicant respectfully traverses.

The Office action makes reference to multiple embodiments of Seymour II to support this rejection. However, Applicant submits that none of the identified embodiments teach each and every element of claims 1 and 12. For example, the Office Action refers to testing disks 14 and 1734. However, no "testing disk 14" was found or identified in the specification. Moreover, reference numeral 1734 is described as a bore (*see* column 9, line 15 and Figure 11).

In another embodiment, the Office Action states that Seymour II teaches a sample taking means 1913, a cartridge, 1911, and a testing element 1930 (*see* Figure 25) contained within a housing 1914. However, Applicant submits that even if Seymour II did teach such a configuration, it still fails to anticipate claims 1 and 12. For example, Seymour II fails to teach the testing element 1930 as being displaceable within the housing 1914 as required by the claims.

As a result, claims 1 and 12 are not anticipated by Seymour II. Claims 2-3, 8, and 11 are also novel both in view of their dependence on claim 1 and for the subject matter contained therein. Reconsideration and allowance of these claims is therefore respectfully requested.

Process  
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*Rejection of claims 1-3, 8, and 11-12 in view of U.S. Pat. No. 4,770,853 (Bernstein)*

Claims 1-3, 8, and 11-12 were rejected under 35 U.S.C. §102(b) as being anticipated by Bernstein (U.S. Patent No. 4,770,853). Applicant traverses this rejection for at least the following reasons.

Bernstein discloses a device for self contained solid phase immunodiffusion assay having a collection device holder 14 that holds the shaft of the collection device 2 in place. The device also includes a cylindrical tube 13 having one or more sealed reagent compartments 15 and 20, and a lower ligand receptor reaction area 10. After obtaining a test sample, the collection device holder is manually forced downward. When the nodule 4 is in contact with horizontal groove 19, then simultaneously the tip 5 will have broken through the first seal (FIG. 4), mixing with the contents of the first vessel 15, then breaking through seal 7 and emptying its contents into vessel 20.

After an appropriate incubation time, the collection device holder 14 is turned to the right and then manually forced downward. When the nodule 4 is in contact with the groove end 21, then the collection device tip 5 is in contact with the prefilter membrane 25 through the window 11. The reactants flow through holes 21 and 22 of adhesive tape 20 which holds membranes 18 and 19 respectively in place. The holes 21 and 22 restrict the flow of the reactants through a capture membrane 19 and a control membrane 18. When an appropriate volume of fluid has diffused through the membranes, the capture and control membranes are visualized within the holes 21 and 22 respectively by lifting the tab 28 of the adhesive tape 12.

Once again, however, each and every element of claims 1 and 12 is not identified in the disclosure of Bernstein. For example, the "testing means" (identified by the Office Action as reference number 18 in Figure 6) is not displaceable within the "housing" (identified by the Office Action as reference number 13) as claimed. Moreover, the "cartridge" (identified by the Office Action as reference number 15) is not displaceable within the housing as claimed in claim

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As a result, Bernstein fails to anticipate claims 1 and 12. Claims 2-3, 8, and 11 are also submitted to be novel both in view of their dependence on claim 1 and in view of the particular subject matter addressed therein. Reconsideration and withdrawal of the rejection are therefore requested.

Rejection of claims 1, 3, 7, and 10-12 in view of U.S. Pat. No. 4,978,504 (Nason)

Claims 1, 3, 7, and 10-12 were rejected under 35 U.S.C. 102(b) as being anticipated by Nason (U.S. Patent No. 4,978,504). Applicant respectfully traverses this rejection for at least the following reasons.

For example, the Office Action equates the claimed "cartridge" to the cylindrical cap 30 and the claimed "testing means" to the glass vial 70 (it is assumed that the Office Action equates the claimed "housing" with the housing member 14 of Nason). However, the glass vial 70 of Nason is not displaceable within the housing member 14 as recited in claims 1 and 12. Rather, the glass vial "testing means" is merely coupled to an end of the cylindrical cap opposite the housing member (see Figure 17).

Moreover, the glass vial 70 is not a testing means but rather appears to be a device for collecting the specimen for use in post analysis, e.g., for use with optical detection methods such as the slide of Figure 15.

As a result, Nason fails to anticipate claims 1 and 12. Claims 3, 7, and 10-11 are also submitted to be novel both in view of their dependence on claim 1 and in view of the particular subject matter addressed therein.

The 35 U.S.C. §103 Rejection

Claim 7 was rejected under 35 U.S.C. §103 as being unpatentable over Bernstein in view of Berger (U.S. Patent No. 4,269,237). Applicant traverses this rejection for at least the following reasons.

(Not displaceable)  
Can be inserted into housing member 14

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To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the documents themselves or in the knowledge generally available to one of ordinary skill in the art, to combine document teachings. Second, there must be a reasonable expectation of success. Finally, the prior art documents must teach or suggest all the claim limitations. See MPEP §2142.

Applicant submits that, for the reasons discussed above with respect to the 35 U.S.C. §102(b) rejection in view of Bernstein, each and every element of claim 1 (from which claim 7 depends) is not identified in the disclosure of Bernstein. For example, neither the testing means nor the cartridge are displaceable within the housing as claimed. No teaching is identified within Berger that remedies these deficiencies.

Moreover, Applicant submits that the Office Action has failed to provide any suggestion to combine the teachings of Bernstein (directed to a device for self contained solid phase immunodiffusion assay) with those of Berger (directed to sump oil draining and collecting device for use with a motor vehicle). Without such a showing, *prima facie* obviousness is unsupported.

For at least these reasons, it is requested that the rejection of claim 7 be reconsidered and withdrawn.

**Allowable Subject Matter and New Claims**

Claims 4-6 and 9 were indicated as allowable if rewritten to overcome the 35 U.S.C. §112, second paragraph, rejections and to include all the limitations of the base and intervening claims. These claims have been canceled and their respective subject matter introduced in new independent claims 13-16. Consideration and allowance of these new claims are respectfully requested.

Applicant further requests entry and consideration of new claims 17-21. These claims find support in the specification as originally filed. For example, claims 17 and 18 include subject matter originally found in claims 4 and 6, respectively. Claims 19 and 20 find support in

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the specification, *see e.g.*, at pages 3-6 and Figures 1, 4, and 5. The method of claim 21 is described in the specification as well, *see e.g.*, pages 6-8 and Figures 1, 4, and 5. Consideration and allowance of these claims are respectfully requested.

**Summary**

It is respectfully submitted that the pending claims 1-3, 7-8, and 10-21 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
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**CERTIFICATE UNDER 37 CFR §1.10:**"Express Mail" mailing label number: EV 073 730 646 USDate of Deposit: 13 MAY 2002

The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Sue Dombroske  
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**APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS  
INCLUDING NOTATIONS TO INDICATE CHANGES MADE**

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Docket No.: 258.0004 0101

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Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

**In the Claims**

For convenience, all pending claims are shown below.

1. (AMENDED) A device for taking and examining samples, comprising a housing (50) in which a cartridge (30), a testing means (40) and a sample-taking means (10) are positioned, wherein the cartridge (30) is displaceable within the housing (50) [in such a manner that] such that a sample introduced by means of the sample-taking means (10) [can be mixed] is operable to form a sample mixture with a content of the cartridge (30), and wherein the testing means (40) is displaceable within the housing (50) [in such a manner that] such that the testing means (40) can be brought in contact with the sample mixture for analyzing the sample mixture.
2. (AMENDED) The device according to claim 1, wherein the sample-taking means (10) [can be] is operable to be introduced into an open end of the housing (50) and [preferably] further wherein the sample-taking means (10) comprises a [steep] thread (18) which cooperates with a corresponding [internal] thread (53) in the housing (50).
3. (AMENDED) The device according to claim 1, wherein [the] a sample-facing end of the sample-taking means (10) comprises a sample chamber (20).
- 4.-6. (CANCELED)
7. (AMENDED) The device according to [any one of] claim[s] 1, wherein one end of the cartridge (30) comprises an opening (32) which can be closed by means of a ball (33).

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8. (AMENDED) The device according to [any one of the] claim[s] 1, wherein the cartridge (30) has a bottom (34) [which can] operable to be perforated.
9. (CANCELED)
10. (AMENDED) The device according to [any one of] claim 1 [to 9], wherein the testing means has the shape of a cylinder [whose cartridge-facing] and has an end that tapers in the form of a truncated cone (41), wherein a [and the] tip thereof has [preferably] an opening (42).
11. (AMENDED) The device according to [any one of] claim[s] 1, wherein the testing means (40) [can be] is operable to be brought in contact with the content of the cartridge (30) if the sample-taking means (10) is arranged in the housing.
12. (AMENDED) A kit for preparing a ready-to-use device for taking and examining samples comprising :
- (a) a sample-taking means (10) for taking a sample;
  - (b) a housing (50) with a cartridge (30) arranged therein[,]; and
  - (c) a testing means (40),
- wherein the sample-taking means (10) and the testing means (40) are introducible into the housing (50) and the testing means (40) [can additionally] is operable to be displaced after having been introduced into the housing (50).
13. (NEW) A device for taking and examining samples, comprising a housing having positioned therein a cartridge, a testing means, and a sample-taking means, the sample-taking means comprising two half-tubes connected to each other, wherein the cartridge is displaceable within the housing such that a sample introduced by the sample-taking

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means is operable to form a sample mixture with a content of the cartridge, and wherein the testing means is displaceable within the housing such that the testing means can be brought into contact with the sample mixture.

14. (NEW) The device according to claim 13, wherein at least one of the two half-tubes comprises a first disk and a second disk defining a sample chamber.
15. (NEW) The device according to claim 14, wherein the first disk comprises a sieve and an indentation, and further wherein an edge of the first disk comprises a cone-shaped ring.
16. (NEW) The device according to claim 15, wherein the cartridge is cylindrically shaped and comprises, on one end, a truncated cone engageable with the cone-shaped ring.
17. (NEW) The device of claim 13, wherein the two half-tubes are connected by a joint, and wherein the joint is selected from the group consisting of a film hinge and an elastic web.
18. (NEW) The device of claim 14, wherein the first disk is coupled to the sample-taking means with predetermined breaking points.
19. (NEW) A device for taking and examining samples, comprising:
  - a housing having a first end, a second end, and a passageway extending between;
  - a cartridge operable to be received in the first end of the housing, wherein the cartridge is displaceable within the passageway of the housing;
  - a sample-taking means operable to be at least partially received in the first end of the housing, wherein a sample introduced by the sample-taking means is operable to form a sample mixture with contents of the cartridge; and

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a testing means operable to be received in the second end of the housing, wherein the testing means is displaceable within the passageway of the housing such that the testing means can be brought in contact with the sample mixture.

20. (NEW) The device of claim 19, wherein the sample-taking means couples to the first end of the housing.
21. (NEW) A method for taking and examining samples, comprising:
- collecting a sample in a sample-taking means;
  - coupling the sample-taking means to a first end of a housing, the housing having a cartridge located therein;
  - displacing the cartridge relative to the sample taking means;
  - combining the sample and contents of the cartridge to form a sample mixture;
  - providing a testing means at a second end of the housing; and
  - displacing the testing means relative to the housing, whereby the testing means contacts the sample mixture.